

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WAYNE A. REED, individually and as)	
husband and next of kin of decedent,)	
DIANA E. REED,)	Case No.: 1:13-cv-1265 (RWZ)
)	
Plaintiff,)	
)	
v.)	MDL No. 2419
)	Dkt. No. 1:13-md-2419 (RWZ)
AMERIDOSE, LLC, MEDICAL SALES)	
MANAGEMENT, INC., MEDICAL SALES)	
MANAGEMENT SW, INC., GDC)	
PROPERTIES MANAGEMENT, LLC,)	
ARL BIO PHARMA, INC. D/B/A)	
ANALYTICAL RESEARCH LABORATORIES,)	
BARRY J. CADDEN, GREGORY)	
CONIGLIARO, LISA CONIGLIARO CADDEN,)	
DOUGLAS CONIGLIARO, CARLA)	
CONIGLIARO, GLENN A. CHIN,)	
SAINT THOMAS OUTPATIENT)	
NEUROSURGICAL CENTER, LLC,)	
HOWELL ALLEN CLINIC, A PROFESSIONAL)	
CORPORATION, JOHN CULCLASURE, MD,)	
DEBRA SCHAMBERG, RN,)	
SAINT THOMAS WEST HOSPITAL)	
formerly known as ST. HOMAS HOSPITAL,)	
SAINT THOMAS NETWORK, and)	
SAINT THOMAS HEALTH,)	
)	
Defendants.)	

**ANSWER OF SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC,
HOWELL ALLEN CLINIC, A PROFESSIONAL CORPORATION, JOHN W.
CULCLASURE, MD, AND DEBRA V. SCHAMBERG, RN**

For their Answer to the Plaintiff's Original Complaint, the Defendants Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC") and Howell Allen Clinic, a Professional Corporation ("Howell Allen"), John W. Culclasure, MD ("Dr. Culclasure"),

and Debra V. Schamberg, RN (“Ms. Schamberg”) (collectively, the “Defendants”), state as follows:

INTRODUCTION

1. The Defendants admit that the Centers for Disease Control and Prevention (“CDC”) reported that individuals in at least 20 states were affected by the fungal meningitis outbreak and that the outbreak caused 64 deaths. The Defendants admit that the CDC has reported that 751 people have been diagnosed with fungal meningitis, fungal infections, and/or abscesses as part of the outbreak. The Defendants admit, based upon information and belief, that the Decedent, Diana E. Reed, died as a result of fungal meningitis.

2. Admitted, based on public reports from these agencies.

3. The Defendants admit, based upon information and belief, that the New England Compounding Pharmacy, Inc. d/b/a the New England Compounding Center (“NECC”) recalled the steroid after some patients were exposed to contaminated doses.

4. The Defendants admit that STOPNC purchased 2,500 vials of methylprednisolone acetate (“MPA”) from NECC from June through August 2012. The Defendants admit that Dr. Culclasure administered NECC MPA to the Decedent as part of the professional care and treatment provided to the Decedent. The Defendants deny selling MPA to the Decedent or any other patient.

5. Admitted.

6. Admitted.

7. The Defendants admit, based upon information and belief, that the Decedent developed fungal meningitis caused by NECC’s contamination of the

medication. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the death.

PARTIES

8. The Defendants admit, based upon information and belief, the allegations of paragraph 8.

9. Admitted.

10. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10.

11. The Defendants admit, based upon information and belief, that Diana Reed was 56 years old when she died. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11.

12. The Defendants admit, based upon information and belief, the allegations of paragraph 12.

13. The Defendants admit, based upon information and belief, the allegations of paragraph 13.

14. The Defendants admit, based upon information and belief, the allegations of paragraph 14.

15. The Defendants admit, based upon information and belief, the allegations of paragraph 15.

16. The Defendants admit, based upon information and belief, the allegations of paragraph 16.

17. The Defendants admit, based upon information and belief, that Barry Cadden is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. The Defendants admit, based upon information and belief, that Barry Cadden is a citizen and resident of the Commonwealth of Massachusetts. The Defendants admit, based upon information and belief, that Barry Cadden is the President of NECC. The Defendants admit, based upon information and belief, that, until October 2012, Barry Cadden was NECC's Licensed Pharmacist Manager of Record. The Defendants admit, based upon information and belief, that Barry Cadden is a Manager of Ameridose, LLC ("Ameridose"). The Defendants admit, based upon information and belief, that Barry Cadden is the Treasurer and a Director of both Medical Sales Management, Inc. ("MSM") and Medical Sales Management SW, Inc. ("MSMSW"). The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 17.

18. The Defendants admit, based upon information and belief, that Gregory Conigliaro is a citizen and resident of the Commonwealth of Massachusetts. The Defendants admit, based upon information and belief, that Gregory Conigliaro is Vice President, Secretary, Treasurer, registered agent, and a Director of NECC. The Defendants admit, based upon information and belief, that Gregory Conigliaro is a Manager of Ameridose. The Defendants admit, based upon information and belief, that Gregory Conigliaro is the Secretary and a Director of both MSM and MSMSW. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 18.

19. The Defendants admit, based upon information and belief, that Lisa Conigliaro Cadden is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. The Defendants admit, based upon information and belief, that Lisa Conigliaro Cadden is a citizen and resident of the Commonwealth of Massachusetts. The Defendants admit, based upon information and belief, that Lisa Conigliaro Cadden is a Director of NECC. The Defendants admit, based upon information and belief, that, until October 2012, Lisa Conigliaro Cadden was a pharmacist at NECC. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 19.

20. The Defendants admit, based upon information and belief, the allegations of paragraph 20.

21. The Defendants admit, based upon information and belief, the allegations of paragraph 21.

22. The Defendants admit, based upon information and belief, the allegations of paragraph 22.

23. The Defendants admit that STOPNC is a Tennessee, for-profit, limited liability company. The Defendants admit that STOPNC's principal place of business is located on the 9th Floor of the Medical Plaza East office building located at 4230 Harding Pike in Nashville, Davidson County, Tennessee 37205. The Defendants admit that STOPNC's registered agent for service of process is Gregory B. Lanford, MD, 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.

24. The Defendants admit that Howell Allen Clinic, a Professional Corporation is a professional corporation with its principal place of business in Nashville, Davidson

County, Tennessee. The Defendants admit that Howell Allen's registered agent for service of process is Gregory B. Lanford, MD, 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.

25. Admitted.

26. The Defendants deny that Ms. Schamberg resides at 2644 Mossdale Dr., Nashville, Tennessee 37217. The Defendants admit the remaining allegations of paragraph 26.

27. The allegations of paragraph 27 are not asserted against the Defendants. No response is required.

28. Denied.

29. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29.

30. The allegations of paragraph 30 are not asserted against the Defendants. No response is required.

31. The allegations of paragraph 31 are not asserted against the Defendants. No response is required.

32. The allegations of paragraph 32 are not asserted against the Defendants. No response is required.

33. The Defendants admit, based upon information and belief, the allegations of paragraph 33.

34. The Defendants admit, based upon information and belief, the allegations of paragraph 34.

35. The allegations of paragraph 35 are not asserted against the Defendants.
No response is required.

36. The allegations of paragraph 36 are not asserted against the Defendants.
No response is required.

37. The allegations of paragraph 37 are not asserted against the Defendants.
No response is required.

38. Denied.

39. Denied.

40. No response is required to paragraph 40.

41. The Defendants admit that Howell Allen and Saint Thomas Network participated in the operation of STOPNC.

42. No response is required to paragraph 42.

43. No response is required to paragraph 43.

JURISDICTION AND VENUE

44. Admitted, based upon the rulings of the Court to this point in the MDL.

45. Admitted, based upon the rulings of the Court to this point in the MDL.

46. Admitted.

47. The Defendants are without knowledge or information sufficient to form a belief as to the existence of contractual indemnification obligations between NECC and Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC Properties Management, LLC ("GDC"), and MSM. The Defendants admit, based upon information and belief, that some, if not all, of the aforementioned individuals are insureds under NECC's insurance policies.

48. Denied.

49. The Defendants deny that the Honorable F. Dennis Saylor is currently presiding over the MDL. The Defendants admit the remaining allegations of paragraph 49.

50. Denied.

51. The Defendants deny that they ever “insinuated” that they intended to seek relief from the automatic stay for the purpose of pursuing indemnity claims against NECC. The Defendants admit that, in NECC’s bankruptcy case, they have filed proofs of claims and represented themselves as creditors of NECC with indemnity and breach of warranty claims. The Defendants admit that STOPNC sent a letter to NECC dated October 16, 2012. The letter speaks for itself. The Defendants admit that they filed an objection to the NECC Trustee’s motion to set a bar date for filing proofs of claims in NECC’s bankruptcy case. The objection speaks for itself.

52. The Defendants are without knowledge or information sufficient to form a belief as to the meaning of the phrase “predicated upon the contaminated MPA purchased from NECC.” Accordingly, the Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 52.

53. The Defendants admit that they have filed proofs of claims in NECC’s bankruptcy case for indemnification and contribution, among other claims. The Defendants deny that they presently intend to seek relief from the automatic stay to pursue these claims.

54. Denied. The Plaintiff has already filed a proof of claim in NECC's bankruptcy case.

55. Admitted. The order speaks for itself.

56. Denied.

57. Admitted.

58. The Defendants admit that physicians at STOPNC administered MPA to patients in Tennessee. The Defendants admit that STOPNC selected and purchased the MPA from NECC. The Defendants deny the remaining allegations of paragraph 58 and specifically deny selling MPA to any patients. The remaining allegations of paragraph 58 are not asserted against the Defendants. No response is required.

59. The Defendants admit that they are subject to the jurisdiction of the District Court for the Middle District of Tennessee. The Defendants deny any and all allegations of wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiff's alleged injuries or damages. The remaining allegations of paragraph 59 are not asserted against the Defendants. No response is required.

60. The allegations of paragraph 60 are not asserted against the Defendants. No response is required.

STATEMENT OF FACTS

Relevant Background

61. The Defendants admit that NECC has filed for bankruptcy. The Defendants admit that 11 U.S.C. § 362(a)(1) operates as a stay of "the commencement or continuation, including the issuance or employment of process, of a judicial,

administrative, or other action or proceeding against the debtor that was or could have been commenced before the commencement of the case under this title, or to recover a claim against the debtor that arose before the commencement of the case under this title.” The statutory section speaks for itself.

62. Admitted.

63. The Defendants admit, based upon information and belief, the allegations of paragraph 63.

64. The Defendants admit, based upon information and belief, the allegations of paragraph 64.

65. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 65.

66. The Defendants admit, based upon information and belief, that, until at least October 2012, Lisa Cadden was a licensed pharmacist. The Defendants are without knowledge or information sufficient to form a belief as to whether Lisa Cadden compounded medications, including MPA, at NECC.

67. The Defendants admit, based upon information and belief, the allegations of paragraph 67.

68. The Defendants admit, based upon information and belief, that, until at least October 2012, Barry Cadden was a licensed pharmacist, NECC’s President, and NECC’s Pharmacy Manager of Record. The Defendants are without knowledge or information sufficient to form a belief as to whether Barry Cadden compounded medications, including MPA, at NECC.

69. Admitted. The regulation speaks for itself.

70. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 70.

71. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 71.

72. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 72.

73. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 73.

74. The Defendants admit, based upon information and belief, that MSM and/or MSMSW sold and/or marketed NECC products, including MPA. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 74.

75. The Defendants admit, based upon information and belief, that MSM and/or MSMSW sold and/or marketed NECC products through September 2012. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 75.

76. The Defendants admit, based upon information and belief, the allegations of paragraph 76.

77. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 77.

78. The Defendants admit, based upon information and belief, the allegations of paragraph 78.

Claims Against the NECC Related Defendants

79. The Defendants admit that NECC has a now well-known record of adverse events. The Defendants deny that NECC's history of adverse events was well-known prior to the fungal meningitis outbreak. The Defendants admit that, according to the Majority Memorandum for the November 14, 2012, Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints and investigations by the Food and Drug Administration ("FDA") and the Massachusetts Board of Registration in Pharmacy ("Mass. BoP") over the past decade, often focusing on unsterile conditions at NECC's facilities. The Defendants admit that the FDA issued a Warning Letter to NECC in 2006. The Defendants admit that the Warning Letter details problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially-available drugs, and selling misbranded compounded drugs. The Defendants deny that the Warning Letter discusses or identifies any specific incidents of contamination or lack of sterility of NECC's products. The Defendants also deny that the Warning Letter actually identifies problems with the storage of medication at NECC. The Warning Letter only identifies potential problems with sterility and storage that can result when sterile medications are repackaged. The Warning Letter identifies these potential problems because NECC was repackaging Astavin, a medication used in the treatment of colorectal cancers and in ophthalmology. The Warning Letter mentions neither injectable steroids, including MPA, nor any adverse patient reactions caused by NECC medication. The Defendants are without knowledge or information sufficient to form a belief as to how long the FDA's 2006 Warning Letter to NECC has been available on the FDA's website.

80. The Defendants admit that MSM and/or MSMSW distributed marketing materials to customers and potential customers touting the cleanliness of the NECC facility. The Defendants admit that the FDA reported that NECC's internal environmental monitoring program yielded microbiological isolates on multiple occasions between January and August 2012. The Defendants admit that the FDA reported that NECC did not investigate or identify the microbiological isolates, or take corrective actions to prevent contamination of the sterile drug products. The Defendants admit, based upon information and belief, that NECC continued to compound MPA despite these findings. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 80.

81. Denied. As mentioned in response to paragraph 80, the Mass. BoP began its investigation of NECC years before September 26, 2012, and inspected NECC on multiple occasions prior to that date. The Defendants admit, based upon information and belief, that the Mass. BoP began its inspection of NECC in response to the fungal meningitis outbreak on September 26, 2012. The Defendants deny, based upon information and belief, that there were "dozens" of known cases of fungal meningitis at that time. The Defendants further deny that NECC's facility was located in a "strip mall."

82. The Defendants admit that the Mass. BoP reported that, when investigators arrived at NECC's facility on September 26, 2012, NECC employees were cleaning compounding areas and conducting environmental testing. The Defendants admit that the Mass. BoP also reported detecting signs of bleach decontamination in the compounding areas. The Defendants are without knowledge or information sufficient to form a belief as to whether the cleanrooms were "filthy" despite NECC's efforts to clean

the cleanrooms. The Defendants admit that the FDA reported observing a boiler leaking water into puddles soiled with thick white debris and thick black granular material. The Defendants admit that the FDA reported that autoclaves used to sterilize products were discolored, tarnished, and contained visible moisture. The Defendants admit that the FDA reported that the HVAC units on NECC's roof were approximately 100 feet from a recycling facility with large equipment that produced airborne particulates (*e.g.*, dust). The Defendants admit that the FDA reported that an HVAC return behind an autoclave appeared to have dark particulate and white filamentous substances covering the louvers. The Defendants admit that the FDA reported that a metal ledge in the cleanroom used to prepare MPA contained reddish-brown and cloudy substances.

83. The Defendants admit that the FDA reported that NECC's internal environmental monitoring program yielded microbiological isolates on multiple occasions between January and August 2012. The Defendants admit that the FDA reported that NECC did not investigate or identify the microbiological isolates, or take corrective actions to prevent contamination of the sterile drug products.

84. The Defendants admit that the FDA and CDC reported these findings following the FDA's inspection of NECC in October 2012 and completion of subsequent testing.

85. The Defendants are without knowledge or information sufficient to form a belief as to whether the FDA observed "visible contamination of the hoods and rooms used to prepare drug products" at Ameridose. The Defendants admit that the FDA reported observing insects and at least one bird in the part of the building where sterile finished product was packaged and stored. The Defendants admit that the FDA

reported observing tubs containing water in the location of roof leaks located in June 2012 in the roof above the cleanroom. The Defendants admit that the FDA reported that Ameridose failed to investigate observed microbial contamination at least 53 times. The Defendants are without knowledge or information sufficient to form a belief as to whether Ameridose reported any adverse events to the FDA. The Defendants admit that the FDA reported that Ameridose classified at least some adverse event reports as “patient responses” or “non-complaints” and failed to investigate what the FDA described as a “trend of complaints.”

86. Admitted.

87. Admitted.

88. The Defendants admit, based upon information and belief, the allegations of paragraph 88.

89. The Defendants admit, based upon information and belief, that NECC voluntarily surrendered its license on October 3, 2012.

90. Admitted.

91. The Defendants admit, based upon information and belief, the allegations of paragraph 91.

92. The Defendants admit, based upon information and belief, the allegations of paragraph 92.

93. The Defendants admit that the regulation states, in part, that “[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner.” The regulation speaks for itself.

94. The Defendants are without knowledge or information sufficient to form a belief as to when ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories (“ARL”) began conducting sterility testing on samples of MPA compounded by NECC. The Defendants admit, based upon information and belief, that ARL conducted some sterility testing on the three recalled lots of MPA.

95. The Defendants admit, based upon information and belief, that NECC sent multiple samples of MPA to ARL for sterility testing from May through August 2012. The Defendants admit, based upon information and belief, that NECC sent ARL two five mL vials of MPA from Lot #052212012@51, BUD 11/17/12 for sterility testing. The Defendants are without knowledge or information sufficient to form a belief as to the total number of vials in Lot #052212012@51, BUD 11/17/12.

96. The Defendants admit, based upon information and belief, the allegations of paragraph 96.

97. The Defendants admit, based upon information and belief, the allegations of paragraph 97.

98. The Defendants admit that USP 71 recommends testing of 2% or at least 20 vials for lots of greater than 6,000 vials.

99. The Defendants admit, based upon information and belief, that NECC sent ARL two five mL vials of MPA from Lot #08102012@51, BUD 2/6/2013 for sterility testing. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 99.

100. The Defendants admit that at least some of the Microbiology Reports issued to NECC by ARL indicate that a USP 71 compliant sterility testing method was

used. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 100.

101. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 101.

102. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 102.

103. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 103.

104. The Defendants admit, based upon information and belief, that ARL allowed NECC to submit inadequate numbers of samples for sterility testing, which did not comply with USP 71 recommendations. The Defendants are without knowledge or information sufficient to form a belief as to whether ARL allowed any other compounding pharmacies to submit an inadequate number of samples.

105. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 105.

106. The Defendants admit, based upon information and belief, that NECC leased the Framingham, Massachusetts facility on Waverly Street from GDC. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 106.

107. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 107.

108. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 108.

109. The Defendants admit, based upon information and belief, that NECC and Glenn Chin compounded MPA. The Defendants admit, based upon information and belief, that ARL tested MPA. The Defendants admit, based upon information and belief, that NECC distributed MPA. The Defendants admit, based upon information and belief, that MSM and/or MSMSW marketed and sold MPA. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 109.

110. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 110.

NECC and the Risks of Pharmacy Compounding

111. Denied.

112. The Defendants admit that CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections in 2002 and that the “Editorial Note” section states that “[p]urchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that is licensed in their state and that follows appropriate measures to ensure that injectable products are free of contamination.” The Defendants deny that this is the entirety of the publication. The Defendants further deny any suggestion that the existence of the report placed a duty on them or establishes the recognized standard of acceptable professional practice. Further, NECC was licensed by the state of Tennessee and assured the Defendants that it followed measures to ensure injectable products were free of contamination, including USP 797. The Defendants admit that Exhibit A to the Plaintiff’s Complaint is a copy of the report referenced in paragraph 112.

113. The Defendants admit that *USA Today* published an article titled “Safety concerns grow over pharmacy-mixed drugs” and that the article discusses concern among “critics and regulators” that compounding pharmacies “are not held to the same quality and safety rules as FDA-regulated drug companies.” But, the Defendants affirmatively state that the article also notes that (1) “regulators have long allowed [compounding] because ‘the vast majority of pharmacies . . . provide a valuable medical service,’” (2) “proponents say compounding pharmacies overall are safe,” (3) “several states are tightening their rules overseeing firms that compound drugs,” and (4) “the FDA has stepped in when it decides a pharmacy has crossed the line and become a drug manufacturer.” The Plaintiff omitted this language from the Complaint. The Defendants are without knowledge or information sufficient to form a belief as to whether the article was a front-page story. The Defendants deny any suggestion that the existence of a 2005 *USA Today* article placed a duty on them or establishes the recognized standard of acceptable professional practice. The Defendants admit that Exhibit B to the Plaintiff’s Complaint is a copy of the article referenced in paragraph 113.

114. The Defendants admit that the FDA published a study titled “Limited FDA Survey of Compounded Drug Products” in 2006. The Defendants admit that the study reported that the FDA collected 73 finished drug products from compounding pharmacies across the country during unannounced visits, but the FDA excluded 37 of the samples from the study because they were deemed unusable for various reasons. The Defendants admit that the study reported that, of the 36 samples tested, 12 (33%) failed analytic testing, but note further that “[m]ost of the products that failed analysis did so due to sub or super-potency . . . or a lack of uniformity of individual dosage units [and

not because of contamination].” The Defendants also note that the study indicates that its “results . . . suggest a problem with the quality of certain compounded drug products,” and “[t]he majority of the finished compounded product samples analyzed in th[e] survey were hormone therapy products.” The article also states that the “FDA has long recognized that traditional pharmacy compounding serves an important public health function” and that the “FDA has historically exercised enforcement discretion and generally has not taken enforcement action against pharmacies engaged in traditional compounding.” The Defendants deny any suggestion that the existence of a 2006 study of 36 samples, mostly hormone replacements, placed a duty on them or establishes the recognized standard of acceptable professional practice. The Defendants admit that Exhibit C to the Plaintiff’s Complaint is a copy of the report referenced in paragraph 114.

115. The Defendants admit that the FDA published an article titled “The Special Risks of Pharmacy Compounding” in May 2007. The article references adverse events involving compounded products and notes the concern of the FDA over compounding operations operating “clearly outside the bounds of traditional pharmacy.” The article further notes that Steve Silverman, Assistant Director of Center for Drug Evaluation and Research Office of Compliance, said that “doctors may not understand that they are receiving compounded products.” The Defendants deny any suggestion that the existence of the article placed a duty on them or establishes the recognized standard of acceptable professional practice. The Defendants admit that Exhibit D to the Plaintiff’s Complaint is a copy of the article referenced in paragraph 115.

116. The Defendants admit that the FDA posted an educational video on YouTube.com regarding concerns over the quality of compounded drugs. The video

states that “today, more than 30 million prescription drugs are compounded annually - many by honest, hard-working pharmacists who provide a much-needed service to their patients,” and “there are both risks and benefits associated with [compounded drugs].” The Defendants deny any suggestion that the existence of a video on YouTube.com placed a duty on them or establishes the recognized standard of acceptable professional practice. The Defendants admit that the video can be viewed here: https://www.youtube.com/watch?v=kif_rmtlQb0.

117. The Defendants admit that the American Society of Anesthesiologists, the American Society of Health-System Pharmacists (“ASHP”), and other medical societies published a joint report regarding drug shortages, and that the report included an article written by the ASHP with the quote included in paragraph 117. The Defendants further note that the article concluded that “[e]ach health system must determine its philosophy on purchasing from . . . compounding pharmacies.” The Defendants deny any suggestion that one paragraph from an eight-page exhibit to a 52-page report placed a duty on them or establishes the recognized standard of acceptable professional practice. The Defendants admit that Exhibit E to the Plaintiff’s Complaint is a copy of the eight-page exhibit to the 52-page report referenced in paragraph 117.

118. The Defendants admit that the CDC published a report in May 2012 regarding fungal infections arising from medications obtained from a compounding pharmacy and that the report states that “contamination of compounded sterile preparations has caused outbreaks.” The article noted that “[s]ince 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products.” The Defendants note that the article does not address the hundreds of

adverse events associated with products from FDA-registered drug companies. The report further states that “[c]ompounded sterile preparations must be prepared according to aseptic practices recommended by organizations such as the United States Pharmacopeia, as stated in United States Pharmacopeia-National Formulary (3).” The Defendants deny any suggestion that the existence of the report placed a duty on them or establishes the recognized standard of acceptable professional practice. Regardless, NECC represented to the Defendants that it was USP 797-compliant. The Defendants admit that Exhibit F to the Plaintiff’s Complaint is a copy of the report referenced in paragraph 118.

Safe Purchasing Practices Recommended

119. The Defendants admit that the ASHP published Guidelines on Outsourcing Sterile Compounding Services (hereinafter “Outsourcing Compounding Guidelines”), a copy of which was attached to the Plaintiff’s Complaint as Exhibit G. The Defendants admit that the ASHP also published a Contractor Assessment Tool, a copy of which was attached to the Plaintiff’s Complaint as Exhibit H. The Defendants deny that either document applied to STOPNC, imposed a duty upon STOPNC, or establishes the recognized standard of acceptable professional practice. In fact, the Contractor Assessment Tool, by its own terms, “does not purport to establish a standard of care.” Further, both documents are intended for use by hospitals or health systems outsourcing their in-house pharmacy compounding, not ambulatory surgery centers like STOPNC.

120. The Defendants deny that they were required to perform the “due diligence” recommended by the ASHP Outsourcing Compounding Guidelines, and

specifically deny that they were required to take the steps identified in subparagraphs (1) through (5). The Defendants complied with the recognized standard of acceptable professional practice in Nashville, Tennessee, or a similar medical community in purchasing MPA from NECC.

- 1) The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to have an employee or agent visit NECC.
- 2) The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to determine if NECC had product liability lawsuits filed against it.
- 3) The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to determine whether NECC had ever recalled any of its compounded preparations.
- 4) The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to review regulatory surveys conducted of NECC's site, including copies of significant regulatory actions.
- 5) The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to determine whether NECC maintained adequate liability insurance.

121. The Defendants admit, based upon information and belief, that the International Academy of Compounding Pharmacists published the Compounding Pharmacy Assessment Questionnaire in October 2011. The Defendants deny that the

existence of the questionnaire placed a duty on them or establishes the recognized standard of acceptable professional practice. The Defendants admit that Exhibit I to the Plaintiff's Complaint is a copy of the questionnaire.

The Fungal Meningitis Outbreak

122. The Defendants admit, based upon information and belief, that, by September 27, 2012, the Tennessee Department of Health ("Tenn. DoH") in collaboration with the CDC and the North Carolina Department of Health and Human Services, had identified nine total patients with fungal meningitis who had received epidural steroid injections from one of the three contaminated lots of MPA from NECC (Lot #'s 05212012@68, 06292012@26, and 08102012@51).

123. The Defendants admit, based upon information and belief, that on September 18, 2012, a Vanderbilt clinician notified the Tenn. DoH that a patient who had received epidural steroid injections at STOPNC had meningitis along with a cerebrospinal fluid culture positive for *Aspergillus* fungus. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 123.

124. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 124.

125. The Defendants admit, based upon information and belief, that, on September 20, 2012, two patients who had received epidural steroid injections at STOPNC were admitted at Saint Thomas West Hospital with symptoms of meningitis. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 125.

126. Admitted.

STOPNC, Dr. Culclasure, and Ms. Schamberg's
Decision to Purchase MPA from NECC

127. No response to paragraph 127 is required.

128. The Defendants admit that Dr. Culclasure and Ms. Schamberg were involved in the day-to-day management of STOPNC.

129. The Defendants admit that Dr. Culclasure and Ms. Schamberg participated in the decision to purchase MPA from NECC.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Denied.

136. The Defendants admit that STOPNC did not submit individualized prescriptions for each patient's injection of MPA prior to purchasing the MPA from NECC but deny that STOPNC was required to do so. The Defendants affirmatively state that Tennessee law permits anticipatory compounding. See Tenn. Code Ann. § 63-10-204(4)(b).

137. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 137.

138. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 138.

139. The Defendants admit that STOPNC's medication formulary lists Decadron, Depo-Medrol, Solumedrol, and Celestone Soluspan. The Defendants deny that those were the only steroids acceptable for use at STOPNC. The Defendants further deny that STOPNC's formulary prohibited the use of MPA from NECC.

140. The Defendants admit that MPA from a compounding pharmacy is not specifically listed on STOPNC's formulary. The Defendants deny that STOPNC's formulary prohibited the use of MPA from NECC.

141. The Defendants admit that Depo-Medrol is listed on STOPNC's formulary. The Defendants deny that STOPNC's formulary prohibited the use of MPA from NECC.

142. Admitted.

143. Admitted.

144. The Defendants admit, based upon information and belief, that the MPA STOPNC purchased from Clint Pharmaceuticals came from an FDA-registered manufacturer.

145. The Defendants admit that Clint Pharmaceuticals released a statement dated November 4, 2012, containing the language quoted in paragraph 145. However, the Defendant's note that the statement was not released until after the NECC recall.

146. Admitted.

147. Admitted.

148. Denied. STOPNC paid \$6.49 per vial for the order reflected in the June 9, 2011, invoice. Clint Pharmaceuticals sent STOPNC a corrected invoice to replace the invoice attached as Exhibit L to the Plaintiff's Complaint.

149. Denied.

150. Admitted.

151. The Defendants admit that Ms. Schamberg obtained Dr. Culclasure's approval prior to placing STOPNC's first order for MPA from NECC.

152. Admitted.

153. The Defendants admit that STOPNC placed its first order from NECC on either June 10, 2011, or June 14, 2011. The Defendants admit that the order consisted of 500 one (1) mL 80 mg vials of MPA and 200 two (2) mL 80 mg vials of MPA.

154. Admitted.

155. The Defendants admit that the Prescription Order Form has a column titled "Name of Patient." The Defendants admit that STOPNC did not fill in that column but deny that STOPNC was required to do so. The Defendants affirmatively state that Tennessee law permits anticipatory compounding. See Tenn. Code Ann. § 63-10-204(4)(b).

156. The Defendants deny that Dr. Culclasure signed or wrote his name on the June 2011 order form submitted to NECC. The Defendants admit that Dr. Culclasure approved the purchase of MPA from NECC.

157. Admitted.

158. Admitted.

159. Admitted.

160. Admitted.

161. Admitted.

162. The Defendants admit that STOPNC provided NECC with a list of patients from STOPNC's daily patient schedule, as requested by NECC to satisfy Mass. BoP

regulations. For years before dealing with NECC, STOPNC used “Mickey Mouse” and “Minnie Mouse” as placeholders on its daily patient schedules to avoid scheduling appointments when Dr. Culclasure was doing patient consults at Howell Allen. These names had nothing to do with STOPNC’s purchases from NECC. The Defendants deny that mistakenly submitting the name “Mickey Mouse” to NECC caused NECC to contaminate the MPA administered to the Decedent or caused the Decedent any injury.

163. Admitted.

164. Denied. The Court dismissed the Plaintiff’s civil conspiracy claim as a matter of law pursuant to its August 29, 2014, memorandum decision at Dkt. 1360.

165. Denied. Additionally, the Court dismissed the Plaintiff’s civil conspiracy claim as a matter of law pursuant to its August 29, 2014, memorandum decision at Dkt. 1360.

166. Denied. Additionally, the Court dismissed the Plaintiff’s civil conspiracy claim as a matter of law pursuant to its August 29, 2014, memorandum decision at Dkt. 1360.

**The Decedent is Injected with MPA from NECC,
Develops Fungal Meningitis, and Dies**

167. The Defendants are without knowledge or information sufficient to form a belief as to whether the Decedent was active prior to her death. The Defendants deny that the Decedent was in good health prior to her death. The Decedent’s medical records demonstrate that the Decedent was burdened with headaches, neck pain, depression, and irritable bowel syndrome. The Defendants are without knowledge or information sufficient to form a belief as to the cause of the Decedent’s neck pain. The Defendants admit, based upon information and belief, that the Decedent underwent

physical therapy and trigger point injections for her neck pain. The Defendants admit that Dr. Lanford concluded from the magnetic resonance imaging studies that the Decedent had multi-level facet disease without significant cord or root compression. The Defendants deny all allegations inconsistent with the foregoing.

168. Admitted.

169. Admitted.

170. Admitted.

171. Admitted.

172. The Defendants admit that they did not contact the Decedent between September 20, 2012, and September 23, 2012. As required by the acceptable standards of professional practice, STOPNC worked closely with the Tenn. DoH during the initial days of this complicated outbreak and relied on the Tenn. DoH's expertise for direction regarding contacting patients. The Defendants are without knowledge or information sufficient to form a belief as to whether or not any other parties or nonparties attempted to contact the Decedent on those days.

173. The Defendants admit, based upon information and belief, that the Decedent was admitted at Saint Thomas West Hospital¹ on September 23, 2012. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 173.

174. The Defendants admit, based upon information and belief, that the Decedent died on October 3, 2012. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 174.

¹ F/K/A St. Thomas Hospital.

175. Admitted.

176. Admitted.

177. Admitted.

178. The Defendants admit that government investigators reported finding *Exserohilum rostratum* in vials of NECC MPA.

179. Admitted.

180. The Defendants admit, based upon information and belief, that the contaminated MPA from NECC caused the Decedent to contract fungal meningitis, suffer a stroke, and die. The Defendants deny any and all allegations of wrongdoing and further deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiff's or the Decedent's alleged injuries or damages.

181. The Defendants deny that the Plaintiff ever "knew" that the Plaintiff's alleged injuries or damages were the result of wrongful or tortious conduct by these Defendants because these Defendants did not engage in any wrongful or tortious conduct. The Defendants deny any and all allegations of wrongdoing and further deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiff's alleged injuries or damages. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 181.

CAUSES OF ACTION

COUNT I CIVIL CONSPIRACY

182. to 186. The Court dismissed the Plaintiff's civil conspiracy claim by memorandum decision issued August 29, 2014, at Dkt. 1360. No response is required.

COUNT II
DUTY TO PREVENT FORESEEABLE HARM BY NECC
(Against Tennessee Defendants)

187. All responses above are incorporated herein by reference.

188. The Defendants admit that that the Decedent did not select the supplier of the MPA used in her procedures. The Defendants are without knowledge or information sufficient to form a belief as to the Decedent's reliance.

189. Denied.

190. Denied.

191. Denied.

192. The Defendants are without knowledge or information sufficient to form a belief as to whether NECC's actions described in paragraph 192 amounted to "intentional misconduct." However, the Defendants do affirmatively assert the comparative fault of NECC, as set forth in their Answer to the Master Complaint.

193. Denied.

194. Denied.

195. Denied.

COUNT III
NEGLIGENCE
(Against NECC Related Defendants)

196. to 202. The allegations of paragraphs 196 to 202 are not asserted against the Defendants. No response is required.

**COUNT IV
NEGLIGENCE PER SE
(Against all NECC Related Defendants except ARL)**

203. to 206. The allegations of paragraphs 203 to 206 are not asserted against the Defendants. No response is required.

**COUNT V
NEGLIGENT SUPERVISION
(Against NECC Related Defendants)**

207. to 211. The allegations of paragraphs 207 to 211 are not asserted against the Defendants. No response is required.

**COUNT VI
Public Nuisance
(Against Barry Cadden, Gregory Conigliaro and GDC)**

212. to 219. The allegations of paragraphs 212 to 219 are not asserted against the Defendants. No response is required.

**COUNT VII
PRODUCT LIABILITY CLAIMS
(Against STOPNC and Howell Allen)**

Pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all product liability claims against Defendants other than STOPNC, including Howell Allen, have been dismissed.

220. Admitted.

221. Admitted.

222. The Defendants admit that the section imposes an automatic stay with various exceptions. The statutory section speaks for itself.

223. The Defendants admit that the Plaintiff could have filed suit against NECC before December 21, 2012.

224. The Defendants admit that 11 U.S.C. § 362(a)(1) operates as a stay of “the commencement or continuation, including the issuance or employment of process, of a judicial, administrative, or other action or proceeding against the debtor that was or could have been commenced before the commencement of the case under this title, or to recover a claim against the debtor that arose before the commencement of the case under this title.” The statutory section speaks for itself.

225. The Defendants admit, based upon information and belief, that NECC is not presently compounding medications.

226. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 226.

227. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 227.

228. Denied.

229. Denied.

230. Admitted. The Court’s order speaks for itself.

231. Admitted.

232. The Defendants admit, based upon information and belief, that at least some of the MPA from NECC was contaminated. The Defendant’s admit, based upon information and belief, that the MPA was in substantially the same condition when it was administered to the Decedent as when it left NECC. MPA purchased from NECC arrived in sealed packages containing sealed individual vials labeled as injectable. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants deny the suggestion that they engaged in any

wrongdoing in procuring the MPA or in administering the MPA during the Decedent's procedures.

233. The Defendants admit that STOPNC charged the Decedent and/or her insurer for the professional services associated with her epidural steroid injections. The Defendants deny that STOPNC charged the Decedent and/or her insurer for the MPA itself. The Defendants admit that Exhibit R to the Plaintiff's Complaint appears to be a copy of the Decedent's billing records from STOPNC.

234. The Defendants admit that Howell Allen charged the Decedent and/or her insurer for the professional services of Dr. Culclasure associated with her epidural steroid injections.

235. Admitted.

236. Denied.

237. Denied.

238. Denied.

239. The Defendants deny that NECC cannot be served with process. NECC can be served with process under the Tennessee Long-Arm Statute, codified at Tenn. Code Ann. § 20-2-225. Upon the filing of a motion for relief from the automatic stay, the Plaintiff's claims can be pursued against NECC. The Defendants deny that the Plaintiff can pursue products liability claims against the Defendant healthcare providers.

240. The Defendants deny that the Plaintiff can pursue products liability claims against the Defendant healthcare providers.

241. The Defendants admit, based upon information and belief, that at least some of the MPA from NECC was contaminated. The Defendants deny any suggestion

that they engaged in any wrongdoing in procuring the MPA or in administering the MPA during the Decedent's procedures.

242. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 242.

243. The Defendants deny that they sold or distributed MPA or that they breached any warranty, express or implied, to the Decedent.

244. Denied. The Defendants further deny the suggestion that they engaged in any wrongdoing in procuring the MPA or in administering the MPA during the Decedent's procedures.

**COUNT VIII
OTHER CLAIMS AGAINST STOPNC**

245. Denied.

246. Denied.

247. Denied.

248. Denied.

249. The Defendants deny any and all allegations of wrongdoing and specifically deny the allegations of wrongdoing in paragraph 249, subparagraphs a. through n. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the Decedent's alleged injuries or damages.

250. The Defendants deny any and all allegations of wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of the Decedent's alleged injuries or damages.

251. The Defendants admit that, when STOPNC decided to purchase MPA from NECC, Ms. Schamberg was an employee of Howell Allen and that Howell Allen

provided her to STOPNC as an employed staff member, pursuant to a services agreement. Pursuant to the same services agreement, Dr. Culclasure served as Medical Director at STOPNC when STOPNC decided to purchase MPA from NECC. The Defendants admit that Dr. Culclasure administered NECC MPA to the Decedent. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants admit that if the Plaintiff establishes an employment or agency relationship, STOPNC may be liable for the actions of the employee or agent.

COUNT IX
OTHER CLAIMS AGAINST DR. CULCLASURE AND MS. SCHAMBERG

252. Admitted.

253. The Defendants admit that Dr. Culclasure and Ms. Schamberg were involved in the day-to-day management of STOPNC.

254. Denied.

255. Denied.

256. Denied.

257. Denied.

258. Denied.

259. The Defendants deny any and all allegations of wrongdoing and specifically deny the allegations of wrongdoing in paragraph 259, subparagraphs a. through i. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the Decedent's alleged injuries or damages.

260. The Defendants deny any and all allegations of wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of the Decedent's alleged injuries or damages.

**COUNT X
OTHER CLAIMS AGAINST HOWELL ALLEN**

261. The Defendants admit that Howell Allen operated STOPNC along with Saint Thomas Network. The Defendants assert that Howell Allen cannot be held liable for the actions of STOPNC pursuant to Tenn. Code Ann. § 48-217-101. The Defendants admit that, when STOPNC decided to purchase MPA from NECC, Ms. Schamberg was an employee of Howell Allen and that Howell Allen provided her to STOPNC as an employed staff member, pursuant to a services agreement. Pursuant to the same services agreement, Dr. Culclasure served as Medical Director at STOPNC when STOPNC decided to purchase MPA from NECC. The Defendants admit that Dr. Culclasure administered MPA from NECC to the Decedent. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants admit that if the Plaintiff establishes an employment or agency relationship, Howell Allen may be liable for the actions of the employee or agent.

262. Denied. Additionally, the Defendants assert that Howell Allen cannot be held liable for the actions of STOPNC pursuant to Tenn. Code Ann. § 48-217-101.

263. Denied.

264. Denied.

265. The Defendants deny any and all allegations of wrongdoing and specifically deny the allegations of wrongdoing in paragraph 265, subparagraphs a. through n. The Defendants deny that any of their allegedly wrongful acts or omissions

were a legal cause of the Decedent's alleged injuries or damages. Additionally, the Defendants assert that Howell Allen cannot be held liable for the actions of STOPNC pursuant to Tenn. Code Ann. § 48-217-101.

266. The Defendants deny any and all allegations of wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of the Decedent's alleged injuries or damages.

267. The Defendants assert that Howell Allen cannot be held liable for the actions of STOPNC pursuant to Tenn. Code Ann. § 48-217-101. The Defendants admit that, when STOPNC decided to purchase MPA from NECC, Ms. Schamberg was an employee of Howell Allen and that Howell Allen provided her to STOPNC as an employed staff member, pursuant to a services agreement. Pursuant to the same services agreement, Dr. Culclasure served as Medical Director at STOPNC when STOPNC decided to purchase MPA from NECC. The Defendants admit that Dr. Culclasure administered MPA from NECC to the Decedent. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants admit that if the Plaintiff establishes an employment or agency relationship, Howell Allen may be liable for the actions of the employee or agent.

268. The Defendants admit that Howell Allen appropriately disclosed to patients that it was a member of STOPNC. The Defendants assert that Howell Allen cannot be held liable for the actions of STOPNC pursuant to Tenn. Code Ann. § 48-217-101. All other allegations in paragraph 268 inconsistent with the foregoing are denied.

269. The Defendants assert that Howell Allen cannot be held liable for the actions of STOPNC pursuant to Tenn. Code Ann. § 48-217-101. All allegations in paragraph 269 inconsistent with the foregoing are denied.

270. The Defendants admit that the *Tennessean* published an article on October 17, 2012 containing information from Scott Butler, Chief Administrative Officer at Howell Allen. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 270.

271. Admitted.

272. Admitted.

273. The Defendants admit that STOPNC and Howell Allen use the same phone number, which directs calls to a receptionist who transfers the calls to the proper destination. The Defendants deny that all persons who worked at STOPNC were employees of Howell Allen. The Defendants admit that Dr. Culclasure and Ms. Schamberg were employees of Howell Allen. The Defendants admit that STOPNC personnel used email addresses ending in “@howellallen.com.”

**COUNT XI
OTHER CLAIMS AGAINST SAINT THOMAS WEST HOSPITAL**

274. The allegations of paragraph 274 are not asserted against the Defendants. No response is required.

275. The Defendants admit that STOPNC and Saint Thomas West Hospital both have “Saint Thomas” in their names. The Defendants admit that STOPNC is located in the Saint Thomas Medical Plaza office building but deny that STOPNC is in the same building as Saint Thomas West Hospital. The Defendants are without knowledge or information sufficient to form a belief as to what constitutes the “St.

Thomas Hospital campus.” The remaining allegations of paragraph 275 are not asserted against the Defendants. No response is required.

276. The Defendants deny that Saint Thomas West Hospital’s CEO is on STOPNC’s board. The Defendants admit that Saint Thomas West Hospital’s Medical Director frequently attended STOPNC board meetings. The Defendants admit that STOPNC conducted board meetings in the Saint Thomas West Hospital Board room.

277. The Defendants admit that STOPNC instructed patients with symptoms of meningitis to report to the Saint Thomas West Hospital emergency room. The remaining allegations of paragraph 277 are not asserted against the Defendants. No response is required.

**COUNT XII
OTHER CLAIMS AGAINST SAINT THOMAS²**

278. The Defendants admit that Howell Allen and Saint Thomas Network are members of STOPNC and that both participated in the operation of STOPNC.

279. Denied as to Howell Allen.

280. Denied as to Howell Allen.

281. The allegations of paragraph 281 are not asserted against the Defendants. No response is required.

282. The Defendants deny that the persons who decided to procure MPA from NECC were employees of Saint Thomas. The remaining allegations of paragraph 282 are not asserted against the Defendants. No response is required.

283. The allegations of paragraph 283 are not asserted against the Defendants. No response is required.

² Saint Thomas Network and Saint Thomas Health are collectively referred to as “Saint Thomas” in the Plaintiff’s complaint.

284. The Defendants admit that STOPNC and Saint Thomas West Hospital both have “Saint Thomas” in their names. The Defendants admit that STOPNC is located in the Saint Thomas Medical Plaza office building but deny that STOPNC is in the same building as Saint Thomas West Hospital. The Defendants are without knowledge or information sufficient to form a belief as to what constitutes the “St. Thomas Hospital campus.” The Defendants admit that Saint Thomas handles STOPNC’s contracting and finances. The Defendants admit that STOPNC instructed patients with symptoms of meningitis to report to the Saint Thomas West Hospital emergency room. The remaining allegations of paragraph 284 are not asserted against the Defendants. No response is required.

285. Denied.

286. Denied.

DAMAGES

287. Denied.

288. The Defendants are without knowledge or information sufficient to form a belief as to the truth of paragraph 288.

289. The Defendants deny that the Plaintiff is entitled to any recovery from them under any legal theory.

290. Denied.

PUNITIVE DAMAGES

291. Denied.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

292. No response is required to paragraph 292.

293. The Defendants deny that the Plaintiff is entitled to any legal recovery from them. The Defendants admit the remaining allegations of paragraph 293. The Act speaks for itself.

294. The Defendants deny that the statutory damages caps codified at Tenn. Code Ann. § 29-39-102 and § 29-39-104 are unconstitutional.

295. The Defendants deny that the Plaintiff is entitled to a declaratory judgment and further deny that the statutory damages caps codified at Tenn. Code Ann. § 29-39-102 and § 29-39-104 are unconstitutional.

296. No response is required to paragraph 296.

**PLAINTIFF'S COMPLIANCE WITH TENN. CODE
ANN. § 29-26-121 AND § 29-26-122**

297. The Defendants deny that the Plaintiff has complied with Tenn. Code Ann. § 29-26-121, as set forth more fully in their Motion to Dismiss at Dkt. 770. The Defendants acknowledge that the Court denied the Motion to Dismiss in part, but hereby reserve, do not waive, and reassert any and all defenses previously asserted based on the Plaintiff's failure to comply with Tenn. Code Ann. § 29-26-121, and adopt and incorporate all previous motions to dismiss or identification of § 29-26-121 and § 29-26-122 defenses as if stated fully herein.

298. The Defendants deny that the Plaintiff has complied with Tenn. Code Ann. § 29-26-121. The Defendants admit that Exhibit V to the Plaintiff's Complaint appears to include copies of the notice letters sent to the Defendants and certificates of mailing sent to the Defendants.

299. The Defendants admit that the Plaintiff sent notice letters to STOPNC as described in paragraph 299. The Defendants deny that the notice letters complied with Tenn. Code Ann. § 29-26-121.

300. The Defendants admit that the Plaintiff sent notice letters to Howell Allen as described in paragraph 300. The Defendants deny that the notice letters complied with Tenn. Code Ann. § 29-26-121.

301. The Defendants admit that the Plaintiff sent notice letters to Dr. Culclasure as described in paragraph 301. The Defendants deny that the notice letters complied with Tenn. Code Ann. § 29-26-121.

302. The Defendants admit that the Plaintiff sent notice letters to Ms. Schamberg as described in paragraph 302. The Defendants deny that the notice letters complied with Tenn. Code Ann. § 29-26-121.

303. The allegations of paragraph 303 are not asserted against the Defendants. No response is required.

304. The allegations of paragraph 304 are not asserted against the Defendants. No response is required.

305. The allegations of paragraph 305 are not asserted against the Defendants. No response is required.

306. Denied.

307. Admitted.

PRAYER FOR RELIEF

A. The Defendants deny that the Plaintiff is entitled to any recovery from them under any legal theory.

B. The Defendants deny that the Plaintiff is entitled to punitive damages against these Defendants. None of the Defendants' alleged wrongdoing rose to the level of being intentional, fraudulent, malicious, or reckless.

C. The Defendants deny that the Plaintiff is entitled to a declaratory judgment and further deny that the statutory damages caps codified at Tenn. Code Ann. § 29-39-102 and § 29-39-104 are unconstitutional.

D. The Defendants demand a jury of 12 to try this action.

E. The Defendants deny that the Plaintiff is entitled to any recovery from them under any legal theory.

F. The Defendants deny that the Plaintiff is entitled to any recovery from them under any legal theory.

ADDITIONAL PARAGRAPHS

The Defendants hereby adopt and incorporate the section of their Answer to the Master Complaint titled "Additional Paragraphs" as if stated fully herein.

AFFIRMATIVE DEFENSES

The Defendants hereby adopt and incorporate the section of their Answer to the Master Complaint titled "Affirmative Defenses" as if stated fully herein.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

C.J. Gideon, Jr.*

Chris J. Tardio*

Alan S. Bean**

Matthew H. Cline*

315 Deaderick Street, Suite 100

Nashville, TN 37238

Ph: (615) 254-0400

Fax: (515) 254-0459

chris@gideoncooper.com

***Attorneys for the Tennessee Clinic
Defendants***

* Admitted pursuant to MDL Order No. 1.

** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 30th day of September, 2014.

/s/ Chris J. Tardio

Chris J. Tardio